510(k) Summary
As Required by 21 section 807.92 (c) K082574

1. Submitter Name: MEDIHIGHTEC MEDICAL CO., LTD.
2. Address: 4F., No.180, Fu 1st St., Cidu District, Keelung City 20650, Taiwan R.O.C.
3. Phone: 886-2-2451-9988
4. Fax: 886-2-2451-1796
5. E-mail: sales@medihightec.com
6. Contact Person: Mr. Mu-Sheng Hung
7. Date summary prepared: April 7th, 2008

OCT 21 2008

8. Regulation Number: 882.5890; 890.5850
9. Product Code: GZJ; IPF

10. Device Trade or Proprietary Name:

(a) TENS/EMS Combo (Model MH8000)
(b)TENS/EMS Combo (Model MH6000)
(c) EMS (Model MH8100)
(d) EMS (Model MH6100)
(e) TENS (Model MH8200)
(f) TENS (Model MH6200)

11. Device Common or usual name:

(a) TENS/EMS COMBINATON UNIT (Model MH8000)
(b) TENS/EMS COMBINATON UNIT (Model MH6000)
(c) EMS UNIT (Model MH8100)
(d) EMS UNIT (Model MH6100)
(e) TENS UNIT (Model MH8200)
(f) TENS UNIT (Model MH6200)

12. Device Classification Name:

(a) Stimulator, nerve, transcutaneous, for pain relief (21 CFR 882.5890, Product Code GZJ).
(b) Stimulator, muscle, powered (21 CFR 890.5850, Product Code IPF).
(c) Combination of (i) Stimulator, nerve, transcutaneous, for pain relief **AND** (ii) Stimulator, muscle, powered (21 CFR 882.5890; 890.5850, Product Code GZJ; IPF)

13. Substantial Equivalency is claimed against the following device:

(a) The new device MH8000 and MH6000 compared to the predicate devices: Comfy STIM, model EV-806 from Everyway Medical instruments Co., Ltd. 510k# K071951, Product Code: GZJ; IPF.
(b) The new device MH8100 and MH6100 compared to the predicate devices: Comfy EMS, model EV-805 from Everyway Medical instruments Co., Ltd. 510k# K071951, Product Code: IPF.

(c) The new device MH8200 and MH6200 compared to the predicate devices: Comfy TENS, model EV-804 from Everyway Medical instruments Co., Ltd. 510k# K071951, Product Code: GZJ.

14. Description of the Device:

The MH8000 Series, which includes models MH8000, MH8100, MH8200, MH6000, MH6100, MH6200, are Transcutaneous Electrical Nerve Stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of units are controlled by the press buttons. Its intensity level is adjustable according to the needs of patients.

The three models MH8000, MH8100 and MH8200 have the same housing. The three models MH6000, MH6100 and MH6200 have the same housing.

The process to set the parameter and attach lead wires to the six models are also the same. Yet, they have different liquid crystal display and parameters for patients to create their own settings.

The MH8200 and MH6200 are the TENS device with 5 modes and adjustable pulse rate, pulse width and timer. The MH8100 and MH6100 are the EMS device with 3 modes and adjustable pulse rate, pulse width, on time, off time, ramp time and timer, The MH8000 and MH6000 are the combination unit with both TENS and EMS functions, The function can be selected by press buttons. The range of settings are identical to those of MH8200, MH8100, MH6100 and MH6200. The difference on the six units can be identified by the liquid crystal display.

Technological Characteristics, New device vs. Predicate device

		New Device	Predicate Device
1.	510(k) Number	To be Assigned	K071951
2.	Device Name, Model	MH8000/MH6000 TENS/EMS Combo MH8100/MH6100 EMS MH8200/MH6200 TENS	EV-806 TENS/EMS, Comfy Stim EV-805 EMS, Comfy EMS EV-804 TENS, Comfy TENS
3.	Manufacturer	MEDIHIGHTEC MEDICAL CO., LTD.	Everyway Medical Instruments Ltd.
4.	Power Source(s)	9 volt battery type 6F22	9 volt battery type 6F22
	- Method of Line Current Isolation	N/A	N/A
	- Patient Leakage Current -Normal condition -Single fault condition	 1.5uA 1.7uA	
5.	Number of Output Modes	7	7
6.	Number of Output Channels	2	2
	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating
	- Method of Channel Isolation	By TRANSFORMER	By TRANSFORMER
7.	Regulated Current or Regulated Voltage?	5V	5V
8.	Software/Firmware/Microprocessor Control?	Yes	Yes
9.	Automatic Overload Trip?	No	No
10.	Automatic No-Load Trip?	No	No

11.	Automatic Shut Off?	No	No
12.	Patient Override Control?	No	No
13.	Indicator Display:		
	- On/Off Status?	Yes	Yes
	- Low Battery?	Yes	Yes
	- Voltage/Current Level?	Yes	Yes
14.	Timer Range (minutes)	Yes	Yes
15	Pulse Width	The range of Pulse Width control is between 50μS and 300μS.	The range of Pulse Width control is between 50μS and 300μS.
16	Frequency	The range of Pulse Rate control between 2 Hz and 150 Hz.	The range of Pulse Rate control between 2 Hz and 150 Hz.
17	Phase Duration	Pulse Width control is between 50μS and 300μS.	Pulse Width control is between 50μS and 300μS.
18	ON Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step
19	OFF Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step
20	Burst Mode	a. Pulses per buster: 9 b. Burst per second: 2 c. Burst duration: 100 mSec. d. Duty Cycle: 200 mSec.	a. Pulses per buster: 10 b. Burst per second: adjustable, 0.5~5 c. Burst duration: 100 mSec. d. Duty Cycle: adjustable, 50~500 mSec.
21	Compliance with Voluntary Standards?	EN60601-1, EN60601-1-2	EN60601-1, EN60601-1-2
22	Compliance* with 21 CFR 898?	Yes	Yes
23	Weight	162 grams (battery included)	150 grams (battery included)
24	Dimensions	13.6(L)x7(W)x2.7(H)(cm)	10.1(L)x6.1(W)x2.45(H)(cm)
25	Housing Materials and Construction	1. Enclosure: ABS, 94V-1, 80℃, UL Approved. 2. PC board: FR4, 94V-1, 105℃, UL Approved.	1. Enclosure: ABS, 94V-1, 80℃, UL Approved. 2. PC board: FR4, 94V-1, 105□, UL Approved.

Above differences of Technological Characteristics do not pose any new questions of safety and effectiveness.

15. Intended use of the device:

The intended Use of TENS, Model MH8200 and MH6200 TENS is as follows:

This device is an electrical nerve stimulator intended for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is intended for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems

The intended Use of EMS, Model MH8100 and MH6100 EMS is as follows:

The device is an electrically powered muscle stimulator intended for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular this device is intended for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation,

(3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. (4) Muscle re-education, (5) maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

The Intended Use of TENS/EMS COMBO, Model MH8000 and MH6000 TENS/EMS Combination Unit are as follows:

This combination device is intended for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is intended for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems. It is also intended for use medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is intended for use for (1) Relaxing muscle spasms, (2)Increasing local blood circulation, (3) immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

16. Non-Clinical Testing:

Non-Clinical Testing Result: New device MH8000/MH6000 vs. Predicate device EV-806

		New Device	Predicate Device
1.	510(k) Number	To be Assigned	K071951
2.	Device Name, Model	MH8000/MH6000 TENS/EMS Combo	EV-806 TENS/EMS, Comfy Stim
3.	Manufacturer	MEDIHIGHTEC MEDICAL CO., LTD.	Everyway Medical Instruments Ltd.
4.	Power Source(s)	9 volt battery type 6F22	9 volt battery type 6F22
5.	Number of Output Modes	7	7
6.	Number of Output Channels	2	2
	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating
	- Method of Channel Isolation	By TRANSFORMER	By TRANSFORMER
7.	Waveform	Asymmetrical biphasic pulse	Asymmetrical biphasic pulse
8.	Shape	Rectangular	Rectangular
9.	Maximum Output Voltage (+/- 20%)	40.8V @ 500 Ohm	50V @ 500 Ohm
		77.6V @ 2000 Ohm	150V @ 2000 Ohm
		102V @ 10000 Ohm	194V @ 10000 Ohm
10.	Maximum Output Current (+/- 20%)	81.6mA @ 500 Ohm	100mA @ 500 Ohm
		38.8mA @ 2000 Ohm	75mA @ 2000 Ohm
		10.2mA @ 10000 Ohm	19.4mA @ 10000 Ohm
11.	Pulse Width	The range of Pulse Width control is between 50μS and 300μS.	The range of Pulse Width control is between 50μS and 300μS.
12.	Frequency	The range of Pulse Rate control between 2 Hz and 150 Hz.	The range of Pulse Rate control between 2 Hz and 150 Hz.
13.	Maximum Phase Charge	24 micro-coulombs @ 500 Ohm	30 micro-coulombs @ 500 Ohm
14.	Maximum Current Density	1.06mA_{rms}/cm^2@ 500 Ohm	1.33mA_{rms}/cm^2@ 500 Ohm

15.	Maximum Power Density	2.4mW$_{rms}$/cm^2@ 500 Ohm	3.7mW$_{rms}$/cm^2@ 500 Ohm
16.	Burst Mode	a. Pulses per buster: 9 b. Burst per second: 2 c. Burst duration: 100 mSec. d. Duty Cycle: 200 mSec.	a. Pulses per buster: 10 b. Burst per second: adjustable, 0.5~5 c. Burst duration: 100 mSec. d. Duty Cycle: adjustable, 50~500 mSec.
17.	ON Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step
18.	OFF Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step

Non-Clinical Testing Result: New device MH8100/MH6100 vs. Predicate device EV-805

		New Device	Predicate Device
1.	510(k) Number	To be Assigned	K071951
2.	Device Name, Model	MH8100/MH6100 EMS	EV-805 EMS, Comfy EMS
3.	Manufacturer	MEDIHIGHTEC MEDICAL CO., LTD.	Everyway Medical Instruments Ltd.
4.	Power Source(s)	9 volt battery type 6F22	9 volt battery type 6F22
5.	Number of Output Modes	3	3
6.	Number of Output Channels	2	2
	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating
	- Method of Channel Isolation	By TRANSFORMER	By TRANSFORMER
7.	Waveform	Asymmetrical biphasic pulse	Asymmetrical biphasic pulse
8.	Shape	Rectangular	Rectangular
9.	Maximum Output Voltage (+/- 20%)	40.8V @ 500 Ohm	50V @ 500 Ohm
		77.6V @ 2000 Ohm	150V @ 2000 Ohm
		102V @ 10000 Ohm	194V @ 10000 Ohm
10.	Maximum Output Current (+/- 20%)	81.6mA @ 500 Ohm	100mA @ 500 Ohm
		38.8mA @ 2000 Ohm	75mA @ 2000 Ohm
		10.2mA @ 10000 Ohm	19.4mA @ 10000 Ohm
11.	Pulse Width	The range of Pulse Width control is between 50μS and 300μS.	The range of Pulse Width control is between 50μS and 300μS.
12.	Frequency	The range of Pulse Rate control between 2 Hz and 150 Hz.	The range of Pulse Rate control between 2 Hz and 150 Hz.
13.	Maximum Phase Charge	24 micro-coulombs @ 500 Ohm	30 micro-coulombs @ 500 Ohm
14.	Maximum Current Density	1.06mA$_{rms}$/cm^2@ 500 Ohm	1.33mA$_{rms}$/cm^2@ 500 Ohm
15.	Maximum Power Density	2.4mW$_{rms}$/cm^2@ 500 Ohm	3.7mW$_{rms}$/cm^2@ 500 Ohm
16.	Burst Mode	a. Pulses per buster: 9 b. Burst per second: 2 c. Burst duration: 100 mSec. d. Duty Cycle: 200 mSec.	a. Pulses per buster: 10 b. Burst per second: adjustable, 0.5~5 c. Burst duration: 100 mSec. d. Duty Cycle: adjustable, 50~500 mSec.
17.	ON Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step
18.	OFF Time	Adjustable, 2~90 seconds, 1 Sec./ step	Adjustable, 2~90 seconds, 1 Sec./ step

Non-Clinical Testing Result: New device MH8200/MH6200 vs. Predicate device EV-804

		New Device	Predicate Device
1.	510(k) Number	To be Assigned	K071951
2.	Device Name, Model	MH8200/MH6200 TENS/EMS Combo	EV-804 TENS, Comfy TENS
3.	Manufacturer	MEDIHIGHTEC MEDICAL CO., LTD.	Everyway Medical Instruments Ltd.
4.	Power Source(s)	9 volt battery type 6F22	9 volt battery type 6F22
5.	Number of Output Modes	5	5
6.	Number of Output Channels	2	2
	- Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating
	- Method of Channel Isolation	By TRANSFORMER	By TRANSFORMER
7.	Waveform	Asymmetrical biphasic pulse	Asymmetrical biphasic pulse
8.	Shape	Rectangular	Rectangular
9.	Maximum Output Voltage (+/- 20%)	40.8V @ 500 Ohm	50V @ 500 Ohm
		77.6V @ 2000 Ohm	150V @ 2000 Ohm
		102V @ 10000 Ohm	194V @ 10000 Ohm
10.	Maximum Output Current (+/- 20%)	81.6mA @ 500 Ohm	100mA @ 500 Ohm
		38.8mA @ 2000 Ohm	75mA @ 2000 Ohm
		10.2mA @ 10000 Ohm	19.4mA @ 10000 Ohm
11.	Pulse Width	The range of Pulse Width control is between 50μS and 300μS.	The range of Pulse Width control is between 50μS and 300μS.
12.	Frequency	The range of Pulse Rate control between 2 Hz and 150 Hz.	The range of Pulse Rate control between 2 Hz and 150 Hz.
13.	Maximum Phase Charge	24 micro-coulombs @ 500 Ohm	30 micro-coulombs @ 500 Ohm
14.	Maximum Current Density	1.06mA_{rms}/cm^2@ 500 Ohm	1.33mA_{rms}/cm^2@ 500 Ohm
15.	Maximum Power Density	2.4mW_{rms}/cm^2@ 500 Ohm	3.7mW_{rms}/cm^2@ 500 Ohm
16.	Burst Mode	a. Pulses per buster: 9 b. Burst per second: 2 c. Burst duration: 100 mSec. d. Duty Cycle: 200 mSec.	a. Pulses per buster: 10 b. Burst per second: adjustable, 0.5~5 c. Burst duration: 100 mSec. d. Duty Cycle: adjustable, 50~500 mSec.

According to above results of manufacture testing demonstrate that the output characteristics of the new devices are substantially equivalent to those of the three predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

17. Safety and Effectiveness of the device:

This new series is safe and effective as the predicate devices cited above.

(1) The new series device comply with safety standard EN60601-1:1990, Including Amendment A1 (1993) and A2 (1995), A13 (1996), IEC60601-1:1988, Including Amendment A1 (1991) and A2 (1995). Test report number is UT96026 and UT96027, See Chapter 11, C.1.

(2) The new series device comply with EMC compliance standard EN60601-1-2:2001 CISPR 11:1997+A1:1999+A2:2002 Group 1:Class B, IEC61000-4-2:1995+A1:1998+A2:2000, IEC61000-4-3:2002, IEC61000-4-8:1993+A1:2000. Test report number is EM/2007/20045 and EM/2007/20046, See Chapter 11, C.2.

(3) Regarding leakage current, please refer to safety report UT96026 and UT96027, Page 15, Clause 19 and appended table 19.4g, 19.4h and 19.4.h3. See Chapter 11, C.1.

18. Conclusions:

Our MH6000/MH8000 TENS and EMS Combo unit integrates EMS and TENS functions with 7 stimulation modes.

S Mode (Synchronous) and A Mode (Alternative) designed for EMS,

N Mode (Normal), M Mode (Rate and Width Modulation), B Mode (Burst), SD Mode (Width Modulation) and MR Mode (Rate Modulation) designed for TENS.

Press MODE button to select only one stimulation mode, therefore TENS and EMS are used independently for the combination devices.

New devices and Predicate devices are the same in the:

1. Power Source;
2. Number of Output Modes;
3. Number of Output Channels;
4. With Microprocessor Control;
5. Standards;
6. Pulse Width control;
7. Pulse Rate control;
8. ON tome, OFF time, Ramp time; and
9. Waveform Shape.

The difference of new devices and Predicate devices is as follows:

1. Patient Leakage Current;
2. Weight;
3. Dimensions;
4. The Maximum Output Voltage of the new devices is smaller than the Predicate devices;
5. The Maximum Output Current of the new devices is smaller than the Predicate devices;
6. The Maximum Phase Charge of the new devices is smaller than the Predicate devices;
7. The Maximum Current Density of the new devices is smaller than the Predicate devices; and
8. The Maximum Power Density of the new devices is smaller than the Predicate devices.

The maximum output Charge of the new devices is smaller than the predicate devices, so the maximum output Charge will not exceed the safe range.

The minimum phase charge for effectiveness of Transcutaneous Neural Stimulation is 3 micro-coulombs. Please refer to: M. Linzer, and D.M. Long, "Transcutaneous Neural Stimulation for Relief of Pain," IEEE Transactions on Biomedical Engineering, Vol.

BME-23, No. 4, pp. 341-345, July 1976.

References:

The EMS designed for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

The References and studies are as follows:

1. Meryl Roth Gersh, M.M.Sc., P.T., Electrotherapy in Rehabilitation, F.A. Davis Company, 1992

2. Val Robertson, Alex Ward, John Low and Ann Reed, Electrotherapy Explained Principles and Practice, Fourth Edition, Elsevier Ltd, 2006

3. Joseph Kahn, PhD, PT, Principle and Practice of Electrotherapy, Fourth Edition, Elsevier (Singapore) Pte Ltd, 2004

4. Sheila Kitchen MSc PhD DipPT MCSP, Electrotherapy Evidence-Based Practice, Eleventh Edition, Elsevier (Singapore) Pte Ltd, 2004

5. Michelle H. Cameron, M.D., P.T., O.C.S., Jennifer A. Rohl, B.S. , Physical Agents in Rehabilitation, Elsevier Ltd, 2006

The Output Specifications, New devices vs. Predicate devices

		New Device		Predicate Device	
1.	510(k) Number	To be Assigned		K071951	
2.	Device Name, Model	MH8000 TENS/EMS Combo MH8100 EMS MH8200 TENS MH6000 TENS/EMS Combo MH6100 EMS MH6200 TENS		EV-806 TENS/EMS, Comfy Stim EV-805 EMS, Comfy EMS EV-804 TENS, Comfy TENS	
3.	Manufacturer	MEDIHIGHTEC MEDICAL CO., LTD.		Everyway Medical Instruments Ltd.	
4.	Pulse Width	The range of Pulse Width control is between 50uS and 300uS.		The range of Pulse Width control is between 50uS and 300uS.	
5	Frequency	The range of Pulse Rate control between 2 Hz and 150 Hz.		The range of Pulse Rate control between 2 Hz and 150 Hz.	
6	Stimulation Modes				
	For EMS	S Mode (Synchronous)	Stimulation of both channels will occur simultaneously	S Mode (Synchronous)	Stimulation of both channels will occur simultaneously
		A Mode (Alternative)	Stimulation of Channel 1 and Channel 2 will occur alternately.	A Mode (Alternative)	Stimulation of Channel 1 and Channel 2 will occur alternately.
	For TENS	N Mode (Normal)	Continuous output, pulse rate and pulse width are adjustable.	N Mode (Normal)	Continuous output, pulse rate and pulse width are adjustable.
		M Mode (Rate and Width Modulation):	Per cycle time is 1 second. Each cycle contains two phases. During the first 0.5 sec. phase, the Pulse Width runs at 50% of its width setting and Pulse Rate runs at its rate setting, then during the second 0.5 sec. phase, the Pulse Rate runs at 50% of its rate setting and Pulse width runs at its width setting. The cycle is then repeated.	M Mode (Rate and Width Modulation):	Per cycle time is 1 second. Each cycle contains two phases. During the first 0.5 sec. phase, the Pulse Width runs at 50% of its width setting and Pulse Rate runs at its rate setting, then during the second 0.5 sec. phase, the Pulse Rate runs at 50% of its rate setting and Pulse width runs at its width setting. The cycle is then repeated.
		B Mode (Burst)	Burst rate fixed =2Hz Pulse width adjustable, 50~260uS Frequency fixed = 100 Hz	B Mode (Burst)	Burst rate adjustable, 0.5~5 Hz Pulse width adjustable, 50~260uS Frequency fixed = 100 Hz
		SD Mode (Width Modulation):	Pulse Width is modulated over a period of 3 seconds from its original setting value down to 60% of its setting, then modulated over another 3 seconds period at its original value. The cycle is then repeated. Per cycle time is 6 seconds.	SD1 Mode (Width Modulation):	Pulse Width is modulated over a period of 3 seconds from its original setting value down to 60% of its setting, then modulated over another 3 seconds period at its original value. The cycle is then repeated. Per cycle time is 6 seconds.

		MR Mode (Rate Modulation)	Pulse Rate is modulated over a period of 3 seconds from its original setting value down to 60% of its setting, then modulated over another 3 seconds period at its original setting. The cycle is then repeated. Per cycle time is 6 seconds.	SD2 Mode (Rate Modulation)	Pulse Rate is modulated over a period of 3 seconds from its original setting value down to 60% of its setting, then modulated over another 3 seconds period at its original setting. The cycle is then repeated. Per cycle time is 6 seconds.
7	Maximum Output Voltage (+/- 20%)	40V @ 500 Ohm		50V @ 500 Ohm	
8	Minimum Output Voltage (+/- 20%)	0.5V @ 500 Ohm		0.5V @ 500 Ohm	
9	Maximum Output Current (+/- 20%)	80mA @ 500 Ohm		100mA @ 500 Ohm	
10	Minimum Output Current (+/- 20%)	1mA @ 500 Ohm		1mA @ 500 Ohm	
11	Maximum Phase Charge	40V÷500ohm×300uSec.=24 micro-coulombs @ 500 Ohm		50V÷500ohm×300uSec.=30 micro-coulombs @ 500 Ohm	
12	Minimum Phase Charge	0.5V÷500ohm×50uSec.=0.05 micro-coulombs @ 500 Ohm		0.5V÷500ohm×50uSec.=0.05micro-coulombs @ 500 Ohm	

The Phase Charge (micro-coulombs) =Amplitude (V) ÷ Load (ohm) × Pulse Duration (uS). The amplitude is the size of the stimulus applied. It is measured either as the stimulus voltage or current. Stimulus voltages used clinically are typically in the range 10V to 100V or more. Stimulus currents are typically in the range 10mA to 100mA for clinical treatments. The amplitude is usually set according to the patient's level of comfort and to the aims of a treatment (refer to References 2., 3. and 4.). Recommended parameters for electrical stimulation to produce muscle contractions: Pulse duration 150 to 200uS for small muscles, 200 to 350uS for large muscles. Frequency 35 to 80Hz, Amplitude is "to contraction" (refer to References 5.). Stimulus parameters used for treatment: Pulse duration 200 to 300uS. Frequency 24 to 80Hz, Amplitude is 30 to 80mA (refer to References 1.).

According to the References, the amplitude is usually set according to the patient's level of comfort and to the aims of a treatment, therefore the effectiveness of EMS is decided by frequency and Pulse duration. The new devices have the same frequency and Pulse duration with the predicate devices (see the Output Specifications); and, The phase charge of the new devices is adjustable between 0.05 to 24 micro-coulombs enough demand, therefore the new devices and predicate devices have the same effectiveness.

According to above conclusions, the new devices are substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medihightec Medical Company Limited
% Underwriters Laboratories, Inc.
Mr. Jeffrey D. Rongero
12 Laboratory Drive
Research Triangle, North Carolina 27709

OCT 21 2008

Re: K082514
Trade/Device Name: MH8000 TENS/EMS Combo, MH6000 TENS/EMS Combo, MH8100 EMS, MH6100 EMS, MH8200 TENS, MH6200 TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: October 2, 2008
Received: October 6, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

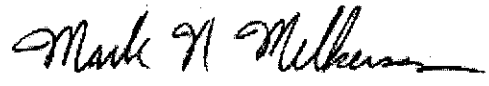
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name:

The MH8000 TENS/EMS Combo, MH6000 TENS/EMS Combo, MH8100 EMS, MH6100 EMS, MH8200 TENS, MH6200 TENS. They are Transcutaneous Electrical Nerve Stimulator (TENS) and Electrical Muscle Stimulator (EMS).

Indications for Use:

APPLICABLE FOR MH8000 (TENS/EMS COMBINATION UNIT) AND MH6000 (TENS/EMS COMBINATION UNIT) AND MH8200 (TENS) AND MH6200 (TENS):
This device is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems.

APPLICABLE FOR MH8000 (TENS/EMS COMBINATION UNIT) AND MH6000 (TENS/EMS COMBINATION UNIT) AND MH8100 (EMS) AND MH6100 (EMS):
This device is an electrically powered muscle stimulator indicated for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is indicated for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

Prescription Use ___X___	And/Or	Over the Counter Use _____.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082514